



March 10, 1998

Dr. Elizabeth Yetley
Director of the Office of Special Nutritionals
Division of Programs and Enforcement Policy
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street HFS-455
Washington, D.C. 20204

Dear Dr. Yetley:

Notice is hereby given pursuant to the requirements of Section 403(r)(6)(21 U.S.C. 343(r)(6) of the Federal Food, Drug and Cosmetic Act of statements of nutritional support which have been made on the label and/or in the labeling in connection with the marketing of the dietary supplement FAMILY ESSENTIALS™ WITH REFERENCE TO ANY CLAIM CONCERNING GINKGO BILOBA. FAMILY ESSENTIALS™ WITH REFERENCE TO ANY CLAIM CONCERNING GINKGO BILOBA was first marketed with these statements of nutritional support on Friday, March 6, 1998. The statements of nutritional support are as follows:

"*Ginkgo Biloba* is perhaps the best documented herb for improved circulation to the brain and the body's extremities.

"*Ginkgo Biloba* the leading herb for improved mental function and vascular circulation".

The *Ginkgo Biloba* (latin name: *Ginkgo Biloba*) herb is an ancient tree species that has survived in China for over 200 million years. Although medicinally used since 2800 BC, it was only in the last 20 years that the leaves of *Ginkgo Biloba* were found to have many beneficial effects on the body's circulatory system.

Ginkgo Biloba is perhaps the best researched of all the herbs. The beneficial effects of *Ginkgo Biloba* are attributed to a combination of principal ingredients known as ginkgo flavo glycosides and triterpene lactones. This Family Essentials™ for Active Seniors multivitamin contains the same standardization level for these ingredients as those used in scientific studies. Most scientific studies of the *Ginkgo Biloba* standardized herbal extract focus on its use in improving blood flow to the brain and to the body's peripheral arteries. Such healthy blood circulation supports memory function and improved mobility in the legs.

Very truly yours,
MASON VITAMINS, INC.

Sonia C. Rodriguez
VP Marketing & Regulatory Affairs

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STUDIES FOR GINKGO BILOBA CLAIMS

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"Phospholipid breakdown and choline release under hypoxic conditions: inhibition by bilobalide, a constituent of *Ginkgo Biloba* Klein, J., Chatterjee, S.S., Loffelholz, K. *Elsevier Science* - 1997 347-350

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"Effects of *Ginkgo Biloba* Extract on Cerebral Functional Activity" Pidoux, B 314-320

STUDIES FOR GINKGO BILOBA CLAIMS

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**“Effects of *Ginkgo Biloba* extract (GBE) on the acute phase of cerebral ischemia due to embolisms” Cahn, J.
Eurotext Ltd © 1985**

“Behavioral effects of *Ginkgo Biloba* extract” Continella G., Drago, F. Eurotext Ltd © 1985

“Effects of *Ginkgo Biloba* extract on two types of cerebral edema” Borzeix, M.G. Eurotext Ltd © 1985

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